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10/540,968	09/26/2005	Wei Sun	046528-5047 (415078)	6096

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EXAMINER

JONES, HUGH M

ART UNIT	PAPER NUMBER
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2128

NOTIFICATION DATE	DELIVERY MODE
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06/10/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbi.com
penelope.mongelluzzo@dbi.com

Office Action Summary

Application No.

10/540,968

Applicant(s)

SUN ET AL.

Examiner

Hugh Jones

Art Unit

2128

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/25/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-10 are pending.

Claim Interpretation

2. The following interpretations are noted: Claims 5, 7-8 are process claims, not product-by-process claims; they are directed to intended use and therefore are provided no patentable weight; Claim 10: “for simultaneously depositing specified hydrogels with different viscosities” refers to intended use – no patentable weight. The claims are directed to a multi-nozzle biopolymer deposition apparatus. “thereby constructing a scaffold from the designed scaffold model” also refers to intended use and is therefore provided no patentable weight.).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-10 are rejected under 35 U.S.C. 102(e) as clearly anticipated by Boland et al. (US 7,051,654).

5. Boland discloses:

1. A process for manufacturing complex parts and devices comprising:
 - (a) utilizing a CAD environment to design a part or device to be created *and*
 - (b) converting the CAD designed part or device into a heterogeneous

material and multi-part assembly model which can be used for multi-nozzle printing; and

Col. 14:

Using the techniques described above, it has been discovered that cells may be printed onto a substrate and remain viable. However, not only does the present invention provide a mechanism for ensuring cell survival, it also provides the ability to easily, quickly, and inexpensively manipulate the types of patterns, densities, etc., that may be printed. For instance, the printed patterns may be simple or complex, and have a shape that is regular or irregular. In fact, due to the control provided by the present invention, there is essentially no limit on the patterns or shapes capable of being printed according to the present invention.

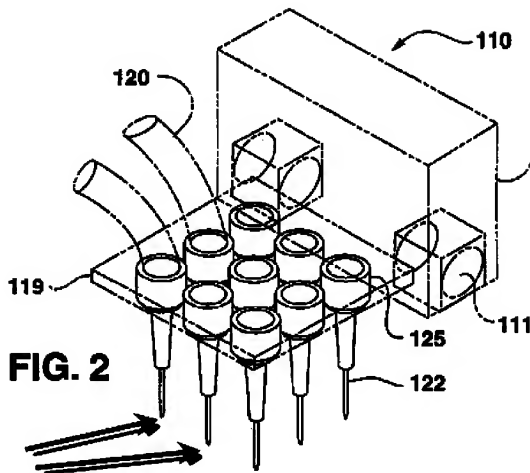
Col. 15:

Regardless of the pattern and/or density selected, the present invention may utilize various control techniques to ensure that the desired results are achieved. Unlike conventional techniques for printing cells that involve contact-deposition, the present invention provides a precise, well-controlled method of printing that does not substantially risk contamination. The non-contact, ink-jet printing techniques employed in the present invention also allow for better control than previously realized when depositing viable cells onto a substrate. Generally speaking, any well-known ink-jet printing control technique may be utilized in the present invention. For instance, a printer driver may be used to control the movement of the printer head, the movement of the substrate, the voltage delivery to the printer head, etc. Some suitable ink-jet printing control techniques that may be adapted for use in the present invention are described in

Referring to FIG. 8, for instance, a block diagram of one embodiment of a control system that may be used in the present invention is shown. As shown, the system includes a host computer 500 and an ink-jet printer 100 (FIG. 1). In the host computer 500, the exchange of various data and control are generally performed between an OS (Operating System) 501 and application software 502 that operates on the OS 501. Print data is exchanged between the OS 501, the application software 502, and a printer driver 503, and is sent to the printer 110 through the printer driver 503. The present invention is by no means limited to any particular printer driver because, as is well known to those skilled in the art, numerous types of printer drivers may accomplish the same functions desired in the present invention.

2 The flow of data in the process of printing out cell composition(s) from the printer 100 is generally described below. Typically, a user first inputs the desired cell density and pattern into the application software 502. These data signals are then sent to the printer driver 503. The printer driver 503 performs processing for the received signals, and also generally converts them into binary signals. The printer driver 503 sends these signals to the interface, in the host computer 500, which is used for the printer 100 or the interface for a file storage unit or the like. The signals are then sent as output to the interface for the printer 100, and the data signals are sent to controller software 601 in the printer 100. Matching between the set print mode and a printer head 110 is checked. Thereafter, the print data is transferred to engine software 602. In this case, the engine software 602 interprets the received data as data indicating the print mode and the data structure designated by the controller software 601, converts the print data into discharge pulses, and sends them to the printer head 110. With this operation, cell composition(s) are discharged from the printer head 110. The ID information of the printer head 110, the ID information of each cell composition reservoir, etc., are sent to the engine software 602. On the basis of these

(c) printing the designed part or device using multiple, different, specialized nozzles.



Col. 4:

Generally speaking, any known ink-jet printer and/or ink-jet printing system may be incorporated for use in the present invention. Ink-jet printers are typically either “DOD” (Drop-On-Demand) or “continuous” ink-jet printers. In a continuous ink-jet printer, a stream of fluid con-

In addition, various ink-jet printers used to print layers on plastic parts (known as “rapid prototyping”) may also be adapted for use in the present invention. One example of such a printer is the ModelMaker II™ printer available from Solidscape, Inc. (formerly “Sanders-Prototype, Inc.”). The

Col. 6:

15 In the illustrated embodiment, the deposition portion 133 includes a housing 137 into which a fluid flows. To facilitate deposition accuracy, the housing 137 may have a conical shape so the diameter of the housing 137 is about 4 millimeters at the top portion and about 2 millimeters at the bottom portion. From the housing 137, the fluid then flows to a hollow needle or tube 139. The size of the needle 139 depends on the type of fluid, the substrate, the printing pattern, and other factors. However, it is generally desired that the needle 139 is large enough to allow any particulates to pass therethrough without substantial sticking or clogging, but small enough to provide the desired deposition accuracy. For example, in one embodiment the needle 139 is a 30-gauge needle that allows cells up to about 100 micrometers in diameter to pass therethrough without substantial sticking or clogging. Of course, smaller and larger needles 139 are also contemplated in the present invention. For instance, in some embodiments, cells having diameters of up to several hundred micrometers (e.g., cell aggregates) may be printed in accordance with the present invention.

Col. 15:

Regardless of the pattern and/or density selected, the present invention may utilize various control techniques to ensure that the desired results are achieved. Unlike conventional techniques for printing cells that involve contact-deposition, the present invention provides a precise, well-controlled method of printing that does not substantially risk contamination. The non-contact, ink-jet printing techniques employed in the present invention also allow for better control than previously realized when depositing viable cells onto a substrate. Generally speaking, any well-known ink-jet printing control technique may be utilized in the present invention. For instance, a printer driver may be used to control the movement of the printer head, the movement of the substrate, the voltage delivery to the printer head, etc. Some suitable ink-jet printing control techniques that may be adapted for use in the present invention are described in

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Col. 17:

A modified Canon® Bubble Jet 2100 printer was used to print the bacteria cells onto the coverslip substrate. The Canon® printer was modified by removing the rubber rolls and removing the center springs, and tightening the remaining springs designed to advance paper. 35

Microsoft PowerPoint software was used to edit a linear colony array pattern with a 2 drops per millimeter density and 0.13 pt weight (Microsoft® PowerPoint™). A black ink-jet cartridge was emptied of its contents, thoroughly cleaned with a 100% ethanol solution, rinsed using autoclaved water, and dried in a sterilized hood. Thereafter, the cartridge was filled with 1 milliliter of a bacterial printing suspension. 55

A modified HP® DeskJet 550C printer was used to print the bacteria cells onto the microscope slide substrate. The HP® printer was modified with gear mount pillars having closer tolerances, which was accomplished by adding a horizontal support, changing the transistor in the circuit to one with higher amplification, and re-entering the horizontal position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: <http://130.127.152.24>. 40 45 50

2. The process of claim 1 further comprising using Boolean, scaling, smoothing, mirroring, to modify the CAD design prior to conversion into a heterogeneous material and multi-part assembly model.

Col. 14:

Using the techniques described above, it has been discovered that cells may be printed onto a substrate and remain viable. However, not only does the present invention provide a mechanism for ensuring cell survival, it also provides the ability to easily, quickly, and inexpensively manipulate the types of patterns, densities, etc., that may be printed. For instance, the printed patterns may be simple or complex, and have a shape that is regular or irregular. In fact, due to the control provided by the present invention, there is essentially no limit on the patterns or shapes capable of being printed according to the present invention.

Col. 15:

Referring to FIG. 8, for instance, a block diagram of one embodiment of a control system that may be used in the present invention is shown. As shown, the system includes a host computer 500 and an ink-jet printer 100 (FIG. 1). In the host computer 500, the exchange of various data and control are generally performed between an OS (Operating System) 501 and application software 502 that operates on the OS 501. Print data is exchanged between the OS 501, the application software 502, and a printer driver 503, and is sent to the printer 110 through the printer driver 503. The present invention is by no means limited to any particular printer driver because, as is well known to those skilled in the art, numerous types of printer drivers may accomplish the same functions desired in the present invention.

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3. The process of claim 1 wherein in step (a) data taken from MRI, CT or other patient specific data is imported into the CAD environment to design the part or device to be created. Col. 16:

The techniques for printing viable cells in accordance
55 with the present invention may be employed in a wide
variety of applications. One such application is the forma-
tion of genomic and protein expression libraries. For
instance, these libraries typically require high throughput
screening of thousands of bacteria cells to identify specific
60 DNA sequences, investigate gene expression, and/or search
for differentially expressed genes. Patterns of bacteria cells
may also be printed according to the present invention to
build biosensors, such as to monitor environmental compo-
nents and detect toxicological contamination. In addition,
65 artificial chromosome libraries and other cell-based sensors
may also be formed. The present invention may also be
employed in tissue engineering and even organ production.

4. The process of claim 1 wherein a biomimetic and non-biomimetic feature is designed into the part or device.

(Note that plainly stated biomimetics refers to human-made processes, substances, devices, or systems that imitate nature (mimetic: Late Latin *mimeticus*, from Greek *mimētikos*, from *mimeisthai* to imitate, from *mimos* mime; from Gk. *Bio-*, comb. form of *bios* "life, course or way of living"). The non-biomimetic scaffold is used to grow the biomentic (cells/organ) portion.)

In this context, see col. 10:

25 Besides gels, other support compounds may also be
utilized in the present invention. Extracellular matrix
analogs, for example, may be combined with support gels to
optimize or functionalize the gel. One or more growth

55 ✎ The manner in which the support compound and/or cells may be deposited onto a substrate may generally vary. For instance, FIG. 4 is a schematic illustration of one embodiment in which layers are deposited onto a substrate 216 using the printer 100 of FIG. 1. Initially, the substrate 216 is supplied at an end 211 of the feed mechanism 114 (FIG. 1). The wheels 135 of the feed mechanism 114 rotate clockwise, so that the substrate 216 is moved closer to the printer head 110. After reaching the desired position, the wheels 135 stop so that the printer head 110 is positioned to deposit the fluids at the desired location. In this embodiment, three fluids (the same or different) are supplied from reservoir(s) (not shown) to nozzles 210, 212, and 214 of the printer head 110. The printer head 110 may make multiple passes over the substrate 216. For instance, in one embodiment, the printer head 110 moves back and forth in the -x direction to make multiple passes over the substrate 216 as it rests on the feed

5. The process of claim 1 wherein the part or device comprises a tissue engineering device and printing in step (c) involves direct deposition of cells or biological factors.

(intended use for the process. These are process claims, not product-by-process claims. No patentable weight provided; limitation "d" is not considered in view of the ambiguity and Applicant's silence on this issue. Regardless, Boland teaches both direct and non-direct contact. See title: "Ink-jet printing of viable cells"). Col. 17:

✎ A modified HP® DeskJet 550C printer was used to print
the bacteria cells onto the microscope slide substrate. The HP® printer was modified with gear mount pillars having closer tolerances, which was accomplished by adding a horizontal support, changing the transistor in the circuit to one with higher amplification, and re-entering the horizontal position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: <http://130.127.152.24>.

Art Unit: 2128

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screening of thousands of bacteria cells to identify specific
60 DNA sequences, investigate gene expression, and/or search
for differentially expressed genes. Patterns of bacteria cells
may also be printed according to the present invention to
build biosensors, such as to monitor environmental compo-
nents and detect toxicological contamination. In addition,
65 artificial chromosome libraries and other cell-based sensors
may also be formed. The present invention may also be
employed in tissue engineering and even organ production.

Col. 17:

A modified Canon® Bubble Jet 2100 printer was used to
print the bacteria cells onto the coverslip substrate. The
Canon® printer was modified by removing the rubber rolls 35
and removing the center springs, and tightening the remain-
ing springs designed to advance paper.

Boland also discloses that direct contact was standard in the art, and that non-direct has certain
advantages: Col. 15:

Regardless of the pattern and/or density selected, the present invention may utilize various control techniques to ensure that the desired results are achieved. Unlike conventional techniques for printing cells that involve contact-deposition, the present invention provides a precise, well-controlled method of printing that does not substantially risk contamination. The non-contact, ink-jet printing techniques employed in the present invention also allow for better control than previously realized when depositing viable cells onto a substrate. Generally speaking, any well-known ink-jet printing control technique may be utilized in the present invention. For instance, a printer driver may be used to control the movement of the printer head, the movement of the substrate, the voltage delivery to the printer head, etc. Some suitable ink-jet printing control techniques that may be adapted for use in the present invention are described in 15 20 25

6. The process of claim 5 wherein direct cell deposition improves histological accuracy, cell ratios, and spatial patterning of cells in the part or device.

(The limitation is directed to a subjective test and furthermore refers to an intended purpose. However, the consequence appears to be an inherent result of the cause - the direct deposition)

7. The process of claim 1 wherein the part or device produced comprises an artificial organ, a tissue scaffold, an artificial vasculature or channel system, or a sample for cytotoxicity testing.

(intended use for the process. These are process claims, not product-by-process claims. No patentable weight provided).

8. The process of claim 1 wherein the part or device produced comprises a biochip, biosensor, bionic, cybernetic, mechanoactive, or a bioactive tissue scaffold.

(intended use for the process. These are process claims, not product-by-process claims. No patentable weight provided).

9. The process of claim 1 wherein the part or device is used in drug delivery.

(Intended use - no patentable weight provided. The claims are directed to a process for manufacturing complex parts and devices.

10. A multi-nozzle biopolymer deposition apparatus comprising:

(a) a data processing system which processes a designed scaffold model and converts it into a layered process tool path;

(see limitations a, b, of claim 1)

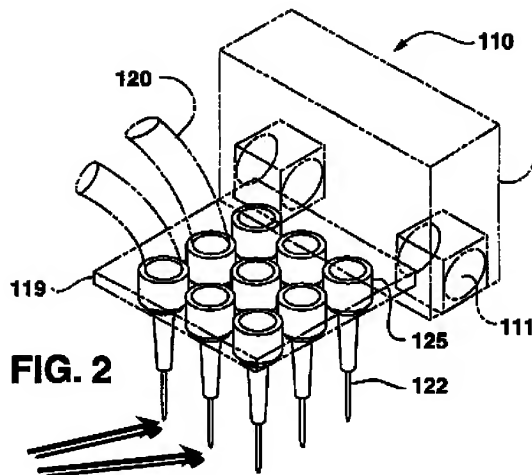
(b) a motion control system driven by the layered process tool path:

(see limitations a, b, of claim 1)

(c) a material delivery system comprising multiple nozzles of different types and sizes for simultaneously depositing specified hydrogels with different viscosities thereby constructing a scaffold from the designed scaffold model.

(“for simultaneously depositing specified hydrogels with different viscosities” refers to intended use – no patentable weight. The claims are directed to a multi-nozzle biopolymer deposition apparatus.”thereby constructing a scaffold from the designed scaffold model” also refers to intended use and is therefore provided no patentable weight.)

See fig. 2:



Regardless, see Col. 17:

position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The 45
printer drivers constantly adjusted the voltages to the
nozzles to account for different impedances of the solutions,
thus allowing the appropriate amount of solution to be
dispensed. The printer drivers are available for download at 50
the following website: <http://130.127.152.24>.

As for scaffolds, see col. 10:

- 25 ~ Besides gels, other support compounds may also be
utilized in the present invention. Extracellular matrix
analogs, for example, may be combined with support gels to
optimize or functionalize the gel. One or more growth
- ~ The manner in which the support compound and/or cells
may be deposited onto a substrate may generally vary. For
instance, FIG. 4 is a schematic illustration of one embodi-
ment in which layers are deposited onto a substrate 216
55 using the printer 100 of FIG. 1. Initially, the substrate 216 is
supplied at an end 211 of the feed mechanism 114 (FIG. 1).
The wheels 135 of the feed mechanism 114 rotate clockwise,
so that the substrate 216 is moved closer to the printer head
110. After reaching the desired position, the wheels 135 stop
60 so that the printer head 110 is positioned to deposit the fluids
at the desired location. In this embodiment, three fluids (the
same or different) are supplied from reservoir(s) (not shown)
to nozzles 210, 212, and 214 of the printer head 110. The
printer head 110 may make multiple passes over the sub-
65 strate 216. For instance, in one embodiment, the printer head
110 moves back and forth in the -x direction to make
multiple passes over the substrate 216 as it rests on the feed

6. Applicant's arguments, filed 3/25/2010, have been carefully considered and are not persuasive.

7. The 112-2 rejection is withdrawn.

8. The 131 affidavit (8/26/2009) is not persuasive. The premise of Applicant's approach is to take their own statement from a 1.132 affidavit, use it in a 131 affidavit and on that basis, allege proof of reduction to practice. This is possible in some situations:

MPEP 715.0137 CFR 1.131 Affidavits Versus 37 CFR 1.132 Affidavits

The purpose of a 37 CFR 1.131 affidavit or declaration is to overcome a prior art rejection by proving invention of the claimed subject matter by applicant prior to the effective date of the reference or activity relied upon in the rejection.

In some situations, an applicant may, alternatively, be able to overcome prior art rejections relying on references or activities which are available as prior art under 35 U.S.C. 102(a) or references which are available as prior art under 35 U.S.C. 102(e) by proving that the subject matter relied upon in the reference or activity was applicant's own invention.

Similarly, where the reference relied upon in a 35 U.S.C. 103 rejection qualifies as prior art only under 35 U.S.C. 102(f) or (g), or, in an application filed on or after November 29, 1999, under 35 U.S.C. 102(e), applicant may be able to overcome this rejection by proving that the subject matter relied upon and the claimed invention were commonly owned or subject to common assignment at the time the later invention was made. See MPEP § 706.02(1)(1) through §1)(3).

However, Applicants have only demonstrated that a figure was provided to Mironov. Mironov is not used in a rejection. Applicants have not demonstrated that the disclosure of Bolland et al. (US 7,051,654) is their own work. In other words, Applicants are taking a 1.132 statement by Applicants about a first disclosure, applying it to a second disclosure, and alleging reduction to

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practice. This is not proof. Applicants have not established that Boland's work is Applicant's own work.

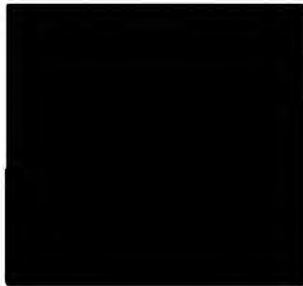
9. Applicants have not established a 'date of invention' of 2/22/2003. Applicants have only established (as per the criterion applicable to 1.132 affidavits) that they provided a drawing of a multi-nozzle printer to Mironov at that time.

10. In this respect, clarification is again requested. The affidavits (8/28/2009 and 3/25/2010) state that the figure in question (that was provided to Mironov) was:

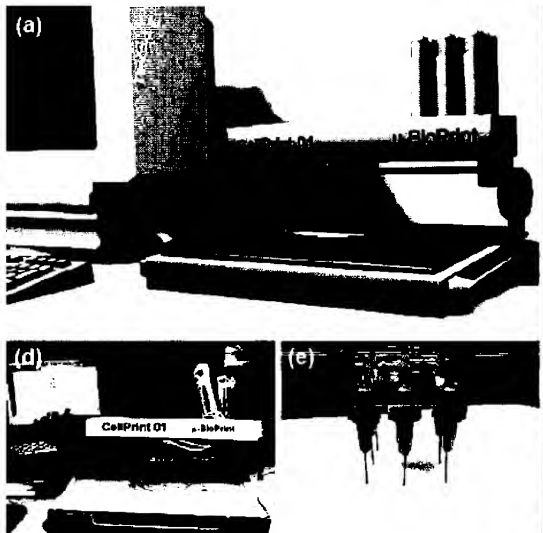
Exhibit B



Exhibit C




However, the figure in Mironov is:



These are clearly different printers. Applicants have been silent. It is also noted that it is not possible to determine the brand of the printer from Applicant's fig. 2 (priority document, 6/29/2005).

11. In any case, Boland discloses that many different types of printers can be used, including Canon and HP models, as noted in the rejection of claim 1. Applicants have not addressed this issue. See col. 4 of Boland:

15 Generally speaking, any known ink-jet printer and/or ink-jet printing system may be incorporated for use in the present invention. Ink-jet printers are typically either "DOD" (Drop-On-Demand) or "continuous" ink-jet printers. In a continuous ink-jet printer, a stream of fluid con-

 In addition, various ink-jet printers used to print layers on plastic parts (known as "rapid prototyping") may also be adapted for use in the present invention. One example of such a printer is the ModelMaker II™ printer available from Solidscape, Inc. (formerly "Sanders-Prototype, Inc."). The

Col. 17:

A modified HP® DeskJet 550C printer was used to print the bacteria cells onto the microscope slide substrate. The HP® printer was modified with gear mount pillars having closer tolerances, which was accomplished by adding a horizontal support, changing the transistor in the circuit to one with higher amplification, and re-entering the horizontal position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: <http://130.127.152.24>.

Col. 17:

A modified Canon® Bubble Jet 2100 printer was used to print the bacteria cells onto the coverslip substrate. The Canon® printer was modified by removing the rubber rolls and removing the center springs, and tightening the remaining springs designed to advance paper.

13. Applicants have made no other arguments against the applied art.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Landers et al. (of record; IDS of 10/26/2007) discloses: